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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,949	12/27/2001	Yusuf K. Hamied	33396-177202	7990
26694	7590	09/07/2004	EXAMINER	
VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP			COLEMAN, BRENDA LIBBY	
P.O. BOX 34385			ART UNIT	
WASHINGTON, DC 20043-9998			PAPER NUMBER	

1624

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,949	HAMIED ET AL.	
	Examiner	Art Unit	
	Brenda Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/540,749.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-19 are pending in the application.

This action is in response to applicant's amendments dated May 20, 2004.

Claims 1, 11, 12 and 16 have been amended.

Response to Arguments

Applicant's arguments filed May 20, 2004 have been fully considered with the following elect:

1. With regards to the objection to the information disclosure statement filed October 8, 2003, it is noted that the reference is now present in the application, however, it is not in the English language and thus cannot be considered. The applicants indicated that the relevance of the reference is identified in the PCT search report, however, this was not seen by the Examiner.
2. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 1-19, the applicants' remarks concerning claims 1-11 were such that the enabling method of claim 16 presents a sufficient basis for supporting compositions of claims 1-11. However, MPEP 2164.01(c) states: When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that use. Hence, claims 1-11 are included in the rejection under 35 U.S.C. § 112, first paragraph.

The applicants' remarks with respect to claim 12 and claims dependent thereon, are such that "these claims are fully supported by the specification". The applicants also stated that the uses of olanzapine are set forth in the various references described and incorporated by reference into the present specification at paragraphs 30-33. The

applicants are reminded that the attempt to incorporate subject matter into this application by reference to the various journal articles spanning paragraphs 32-33 is improper. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification does not have working examples on the use of Forms III, IV or V olanzapine. The absence of working examples is one of the factors to be considered in deciding whether the practice of an invention would involve undue experimentation. There must be evidence to justify the contention that the claimed compounds can be useful in the treatment of "psychotic condition and gastrointestinal conditions". It is difficult to treat many of the disorders claimed herein. Recent studies on experimental and clinical pharmacology of nicotinic acetylcholine receptors cited in Annual Reports in Medicinal Chemistry indicate that the following disorders may be associated with nicotinic acetylcholine receptors: senile dementia of the Alzheimer's type, Parkinson's disease, Huntington's chorea, tardive dyskinesia, hyperkinesia, mania, depression, attention deficit disorder, anxiety, dyslexia, schizophrenia, Tourette's syndrome and smoking cessation. The "nicotinic" effect with respect to Alzheimer's is hypothesized. Parkinson's Disease is "presently of unknown etiology" and recent studies have exhibited dosing problems as well as "unusually high placebo effects". The pathophysiology of Tourette's Syndrome is unknown. The treatment of ulcerative colitis is currently "limited to anti-inflammatories, immunosuppressants and antibiotics". Additionally, there are other pathological non-

CNS conditions, such as pouchitis and influenza virus-induced pneumonitis, where nicotine efficacy has been reported, but remains to be confirmed.

Claims 1-19 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections of claims 2, 4 and 6 in the last office action, which are hereby **withdrawn**.

In view of the amendment dated May 20, 2004, the following new grounds of rejection apply:

Specification

4. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by CHAKRABARTI et al., U.S. 5,229,382. U.S. '382 teaches and claims a pharmaceutical compositions of the instant invention where 2-Methyl-10-(4-methyl-1-piperazinyl)-4H-thieno[2,3-b][1,5]benzodiazepine (olanzapine) is the active ingredient. The definition of polymorph is such that a polymorph is a specific **crystalline form** of a compound that can crystallize in different forms. However, a pharmaceutical composition of a polymorphic form of olanzapine in a non-solid no longer possesses its crystalline characteristics.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Brenda Coleman". The signature is fluid and cursive, with a long horizontal stroke at the end.

Brenda Coleman

Primary Examiner Art Unit 1624

September 2, 2004